

REMARKS

With entry of this amendment, claims 1, 3, 6, 8, 22, 24-26, 31, 34, and 35 are pending in the above-identified application. Claims 2, 4, 5, 7, 9, 14, 15, 18, 20, 21, 23, 27-30, 32, and 33 have been canceled without prejudice to Applicants' right to pursue the subject matter of these claims in a related, copending application. Claims 1, 3, 8, 24, 25 and 31 have been amended and new claims 34 and 35 have been added as set forth in detail below. Support for these amendments is identified in the following remarks. No new matter has been added by these amendments.

Rejections under 35 USC §112

Claims 28-30 are rejected under 35 USC §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants note that the instant rejection is obviated by the cancellation of claims 28-30 as set forth above.

Claims 3-9, 23-27 and 32-33 are rejected under 35 USC §112, first paragraph, as allegedly non-enabling for making and using the breadth of claimed antisense molecules to Nr-CAM for treatment of the claimed cells expressing Nr-CAM in a whole organism, including a human.

Applicants first note that the instant rejection is obviated with respect to claims 4, 5, 7, 9, 23, 27, 32, and 33 in view of the cancellation of these claims without prejudice as set forth above.

With respect to claim 3, while Applicants do not agree with the Examiner's rejection for at least the reasons of record, but in order to further expedite prosecution of the instant application, claim 3 has been amended as follows. Claim 3 now recites "A method of

inhibiting proliferation of a human tumor cell overexpressing Nr-CAM in a subject comprising administering locally to the subject an effective amount of a Nr-CAM antisense nucleic acid comprising the complement of nucleotides 119 to 1434 of SEQ. ID. NO.: 1; wherein the tumor cell comprises a glioblastoma, a glioma, an astrocytoma, or an oligodendroglioma." Applicants note the Examiner has stated, with respect to the administration of pCMV1/3Nr-AS (corresponding to nucleotides 119 to 1434 of SEQ ID NO: 1) that "the specification is considered enabling for the administration to human glioblastoma" (Office Action mailed 5/6/2003, page 10). The Examiner further states that the "specification as filed is enabling for administration of these antisense to glioblastomas by way of injection" (*Id.* at page 6). The Examiner has also indicated claim 3 to be free of the prior art. Applicants believe that injection as used in the specification and examples fully enables methods for local administration which includes injection or administration directly into a tumor overexpressing Nr-CAM and injection or administration into the local area surrounding the tumor either prior to or subsequent surgical removal of the tumor, and similar methods. Tumor cells that overexpress Nr-CAM are defined in the specification to comprise glioblastomas, gliomas, astrocytomas (as noted by the Examiner), and oligodendrogliomas (See Table 2, page 107 of the specification). Therefore, claim 3 as currently amended is believed to be allowable. Claims 6, 8, 24, 25 and 26 should also be allowable at least for the reason that these claims depend from an allowable base claim.

In view of the remarks and amendments set forth above, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 3, 6, 8, and 24-26 for lack of enablement under 35 U.S.C. § 112, first paragraph.

Rejections under 35 USC § 102

Claims 1, 22 and 31 stand rejected under 35 USC §102(b) as allegedly anticipated by Lane *et al.*

While not agreeing with the Examiner's rejection or reasons therefor, but in order to further expedite prosecution of the instant application, Applicants have amended independent claims 1 and 31 to recite that the antisense nucleic acid comprises "at least [[15]] 100 nucleotides" hybridizable to the RNA transcript of the Nr-CAM gene having SEQ ID NO: 1. Support for this amendment is found at, *e.g.*, page 75, lines 27-29, of the specification. Applicants note that Lane *et al.* do not disclose an antisense nucleic acid as presently recited in claims 1 and 31. Therefore, claims 1 and 31 are believed to be allowable over the cited art. Claim 22 should also be allowable at least for the reason that it depends from an allowable claim.

In view of the remarks and amendments as set forth above, Applicants respectfully request the Examiner to reconsider and withdraw the rejections of claims 1, 22, and 31, as anticipated by Lane *et al.* under 35 U.S.C. § 102(b).

Other Amendments

In view of the cancellation of claim 7, as set forth above, claim 8, which recites dependency from claim 7, has been amended to recite dependency directly from independent claim 3. Further, Claim 24 which recites dependency from claim 23, now canceled, has been amended to depend from claim 3 and claim 25 which recites dependency from claim 4 has been amended to depend from claim 24.

New Claims

New claims 34 and 34 have been added to recite particular embodiments of the present invention described in the specification as filed but not previously claimed.

Claim 34 recites an embodiment of the composition of claim 1 in which the antisense nucleic acid comprises the complement of nucleotides 119 to 1424 of SEQ ID NO: 1. Support for claim 34 is found at, *e.g.*, page 109, lines 6-8, of the specification. Claim 35 recites and embodiment of the composition of claim 1 in which the antisense nucleic acid comprises the

complement of nucleotides 1410 to 2746 of SEQ ID NO: 1. Support for claim 35 is found at, *e.g.*, page 109, lines 29 and 30, of the specification.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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